



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

February 19, 2011

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 777-91, Citrus Scent Lysol Brand
Antibacterial Kitchen Cleaner II; DP Barcode: 386205

From: Tajah Blackburn, PhD
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Product Science Branch
Antimicrobials Division (7510P) *2/23/11*

To: Velma Noble PM 31/Tracy Lantz
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Applicant: Reckitt Benckiser, Inc.
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BACKGROUND

The Agency's letter, dated October 9, 2009, requested confirmatory efficacy data without the use of the coarse filtration step. Briefly,

During a recent review of efficacy data provided by Reckitt Benckiser, it became apparent that unapproved protocol deviations were occurring. A "coarse filtration" step was observed and documented as an unapproved deviation that may significantly impact product efficacy. The registrant provided a letter to the Agency (dated August 28, 2009) detailing the deviation; briefly, "Reckitt Benckiser has been employing the use of coarse filtration as part of the preparation of our test cultures for over 10 years. This has been done for every bacterial culture used in testing conducted using the AOAC Use Dilution, the AOAC Germicidal Spray Products as Disinfectants and the ASTM E1153 Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces. The coarse filtration has been described and included in all of our protocols and Standard Operating Procedures (SOPs) which have been reviewed and approved by the Agency both during registration submission reviews and on-site GLP inspection. Currently, the standard test methods cited above specify for the test culture to be vortex mixed and then allowed to sit undisturbed to allow any debris or clumps to settle. The upper portion of the broth is used as

the test culture. The Reckitt Benckiser coarse filtration procedure was designed to simulate this step without the need for settling and removal of the upper portion of the culture broth."

To address this study deviation, the Agency requested confirmatory efficacy data for those studies where the efficacy data was generated prior to the November 11, 2008 Agency letter. The confirmatory efficacy data must include 2 product lots per test organism at 10 carriers per lot. The current submission was provided to in response to the Agency's request. Efficacy data was generated at ATS Labs, located 1285 Corporate Center Drive, Suite 110, in Eagan, MN, 55121.

The data package contained a letter from the registrant (dated December 17, 2010), the referenced Agency letter (dated October 9, 2009), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), and one efficacy study (MRID No. 483300-01).

II SYNOPSIS OF SUBMITTED EFFICACY DATA

1. MRID No. 483300-01, "AOAC Germicidal Spray Method" by Becky Lien. Study Completion Date—December 14, 2010. Study Identification Number—A10295.

The product was tested against *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538), and *Salmonella enterica* (ATCC 10708). Two lots (Lot Nos. 1686-181 and 1686-182) of the product, Lysol Brand II Antibacterial Kitchen Cleaner Formula # 1489-111 were tested using the AOAC Germicidal Spray Method (protocol no. REK01091510.GS). The product was received ready-to-use. Testing was conducted in the presence of 5% fetal bovine serum. Glass slides carriers were inoculated with 10 µl of the test culture. Slides were allowed to dry for 38 and 40 minutes at 35-37°C at 33.49% and 51% relative humidity. Carriers were sprayed with the test substance with 3 pumps at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the disinfectant for 10 minutes at room temperature (20°C and 21°C) at a relative humidity of 40% and 51%. Following exposure, the remaining liquid was drained off. Each medicated carrier was then transferred to 20 ml aliquots of Lethen broth +0.07% lecithin +0.5% Tween 80. The subculture vessels and controls were incubated for 46.25 hours at 35-37°C. Subcultures were examined for the presence or absence of visible growth.

Note: Testing performed on October 6, 2010 which resulted in Lysol Brand II Antibacterial Kitchen Cleaner Formula #1489-111 (Lot No. 1686-182) showing growth in 1 of the 10 tubes when tested against *Staphylococcus aureus*. Retest was conducted against *Staphylococcus aureus* using 60 carriers on October 25, 2010, to test for false positives. What were the results of the false positive in the initial test?

III RESULTS

Lot Number	Test Organism	Test Result (# positive carriers/total carriers)
1686-027	<i>Staphylococcus aureus</i>	0/60
	<i>Pseudomonas aeruginosa</i>	0/60
	<i>Salmonella choleraesuis</i>	1/60
1686-029	<i>Staphylococcus aureus</i>	0/60
	<i>Pseudomonas aeruginosa</i>	0/60
	<i>Salmonella choleraesuis</i>	0/60
1686-032	<i>Staphylococcus aureus</i>	0/60
	<i>Pseudomonas aeruginosa</i>	0/60
	<i>Salmonella choleraesuis</i>	0/60

Staphylococcus aureus— 3.192×10^6 , 1.45×10^6

Salmonella choleraesuis— 2.0×10^4 ,

Pseudomonas aeruginosa— 2.09×10^6 ,

IV CONCLUSIONS

1. The efficacy data cited therein were submitted to address the Agency request outlined in the letter dated October 9, 2009. The submitted efficacy data (MRID No. 483300-01) are acceptable regarding the use of the product, Citrus Scent Lysol Brand Antibacterial Kitchen Cleaner II, as a hospital disinfectant at the ready-to-use preparation in the presence of 5% organic soil for a contact time of 10 minutes when tested against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica*. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. The registrant has provided clarifying information that establishes the relationship between, Lysol Brand All Purpose Cleaner (on registrant's letter), Lysol Brand Antibacterial Kitchen Cleaner (on registrant's letter), and Lysol Brand II Antibacterial Kitchen Cleaner (Formula #1489-111) (MRID No. 483300-01).